

# DEPARTMENT OF VETERANS AFFAIRS Veterans Health Administration Washington DC 20420

IL 12-2003-002

In Reply Refer To: 121

**April 10, 2003** 

#### OFFICE OF RESEARCH AND DEVELOPMENT LETTER

# SOLICITATION OF APPLICATIONS FOR THE MEDICAL RESEARCH SERVICE (MRS) RESEARCH ENHANCEMENT AWARD PROGRAM (REAP)

- 1. This Veterans Health Administration (VHA) Medical Research Service (MRS) Information Letter announces the opportunity for Department of Veterans Affairs (VA) medical centers to compete for support by the Research Enhancement Award Program (REAP).
- 2. MRS REAP awards are intended to support groups of VA investigators in programs of exceptional quality that address specific medical problems of veterans through fundamental, translational, and/or clinical research. Each REAP needs to focus on a medical problem of importance to the veteran population. Potential focus areas of interest for new REAP applications include, but are not limited to:
  - (1) Lymphomas, leukemias, and other hematologic malignancies;
  - (2) Amyotrophic lateral sclerosis;
  - (3) Diagnosis, prevention, or treatment for potentially fatal airborne pathogens or toxins;
  - (4) Fundamental mechanisms of vaccine development;
  - (5) Other deployment related issues;
  - (6) Chronic human viral diseases;
  - (7) Sleep disordered breathing; and
  - (8) Genetic predisposition to solid tumors (e.g., colon cancer, neurofibromatosis, etc.).

**NOTE:** Applications for REAP awards in other focus areas will be accepted, however, each REAP needs to be distinct in research focus from other REAPs and/or ongoing centers at the applying VA medical center.

#### 3. Goals

a. The REAP goals are to promote new and innovative research, foster new research collaborations, and train the next generation of VA medical research investigators.

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- b. To accomplish these goals, REAP funds may be used to support Core Facilities and Pilot Projects that encourage new and innovative research and multiple collaborations among investigators within the REAP.
- c. To advance the training mission, REAP funds may be used to support Associate Investigators or start-up costs of junior faculty. *NOTE:* Recipients of REAP awards are expected to participate in training new investigators and to pursue new avenues for solving medical problems.
- **4. Process.** Applicants for the MRS REAP need to review Attachments A, B, C, and D, which provide the mandated information needed to apply, the deadlines which need to be met, and an application checklist.
- 5. Inquiries. Inquiries may be directed to Dennis A. Przywara, Ph.D., at (202) 408-3600.

Nelda P. Wray, M.D., M.P.H. Chief Research and Development Officer

Attachments

DISTRIBUTION: CO: E-mailed 4/10/2003

FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 4/10/2003

#### **ATTACHMENT A**

#### LETTERS OF INTENT

- 1. Written notification of intent to submit a Research Enhancement Award Program (REAP) application, a Letter of Intent (LOI) must be received in Medical Research Service (MRS) (121E) by **May 12, 2003**. Applications will not be reviewed without this notification.
- 2. The following information may be provided via FAX to REAP LOI at 202-275-6100:
  - a. Name of the VA medical center.
  - b. REAP Director (must be a Qualifying Investigator).
  - c. Application title.
- d. Name of each Qualifying Investigator and the award that fulfills the criteria in Attachment B, Paragraph 2; include award title, funding agency, and inclusive dates.
  - e. Primary research focus area.
  - f. One paragraph describing the scientific approaches of the REAP.
- g. Signatures of the REAP Director, Associate Chief of Staff, Research and Development (R&D), and the Department of Veterans Affairs (VA) medical center Director.
- **3.** The deadline for receipt of applications is August 1, 2003. Proposals will be reviewed in the fall, with earliest funding starts anticipated for January 1, 2004.
- **4. Inquiries.** Inquiries may be directed to Dennis A. Przywara, Ph.D. at (202) 408-3600.

#### ATTACHMENT B

#### PROGRAM DESCRIPTION

1. <u>Research Focus.</u> Each REAP needs to have a central unifying intellectual theme focused on research related to a specific medical problem of veterans. Translational research and active collaborations between basic and clinical scientists are encouraged. Resources for this program are not to be used solely for the purpose of expanding existing research programs; VA medical centers with research centers funded from another source needs to describe a research focus in this application that is distinct from their other funded programs.

# 2. Qualifying Investigators

- a. To apply for REAP support there must be at least <u>four</u> VA Qualifying Investigators. A Qualifying Investigator is defined by fulfilling one of the following criteria:
- (1) VA Merit Review funded Principal Investigator (MRS, Health Services Research and Development (HSR&D) or Rehabilitation Research and Development (RR&D)) at the time of application submission; or
  - (2) MRS Research Career Scientist; or
- (3) VA Career Development awardee at the Advanced Research Career Development (ARCD) level; or
- (4) VA clinician investigator with a history of Merit Review funding and meaningful participation in VA research activities, and current National Institute for Health (NIH) or other Federal competitive research support.
- b. If there are at least three Qualifying Investigators who fulfill the preceding criteria, MRS may consider accepting as a fourth Qualifying Investigator a full-time VA clinician who has a history of meaningful participation in VA research activities and skills highly relevant to translational research proposed for the REAP. Acceptance of a clinician as a Qualifying Investigator is made administratively at MRS, based on information supplied in the Letter of Intent (LOI). *NOTE:* Such an exception is intended to facilitate translational research.
- c. To remain eligible, each REAP needs to maintain at least four Qualifying Investigators throughout the funding period. If at any time during the submission, review, or funding periods, the number of Qualifying Investigators falls below four, MRS must be informed.
- **3.** <u>Director.</u> The REAP Director is responsible for the coordination of all REAP activities. The VA medical center and the Veterans Integrated Services Network (VISN) must support the REAP application and agree to provide a minimum of 25 percent time for the REAP Director to coordinate REAP activities. The Director on a REAP application may not be the Director, Principal Investigator (PI) or Co-PI in any other ongoing MRS-supported REAP or center.

- **4.** <u>Collaborating Investigators.</u> In addition to the Qualifying Investigators, other VA and non-VA basic science or clinical investigators may be included if they contribute to and strengthen the REAP's research focus. These investigators are to be referred to as "Collaborating Investigators." If an investigator's research has been primarily focused on other diseases, disorders, or processes, the nature of the contribution to research in the REAP needs to be clearly defined.
- **5.** New Initiatives (Pilot Projects). Pilot projects need to explore new and innovative research ideas, promote new research collaborations, and provide a platform for training new investigators. Carefully conceived pilot projects are encouraged to explore the next generation of solutions to medical problems at the fundamental, translational, and/or clinical levels. Pilot studies are a vehicle to demonstrate collaboration of qualifying investigators, supporting investigators, and trainees. It is expected that some pilot studies will lead to new research funding. **NOTE:** Pilot studies submitted by non-collaborating individual investigators are not appropriate.
- **6.** <u>Training.</u> Training of junior investigators is one of the major goals of the REAP initiative. It is expected that REAP funds will be used to support Associate Investigator (AI) trainees. *NOTE:* Each AI applicant must be approved by Medical Research Service (see VHA Handbook 1201.2, Associate Investigator Program, for instructions). Involvement of other VA and non VA-supported trainees in the REAP is encouraged. Involvement of Merit Review Entry Program (MREP) and Career Development trainees is particularly encouraged. Qualifying Investigators need to have prior success in training and mentoring pre- and post-doctoral fellows, junior investigators, and be able to present plans for recruiting and training new investigators.
- 7. <u>Core Facilities.</u> REAPs have the option of supporting core activities or specialized shared equipment. Core laboratories and/or facilities may be supported from REAP funds for the benefit of multiple investigators within the REAP. The goal of REAP-supported Core Facilities is to enhance collaborative interactions between all REAP investigators and trainees. Specialized equipment for the core may be requested (see par. 10).
- **8.** <u>Coordination of Activities.</u> In addition to the Director, each REAP is expected to establish an internal executive or steering committee to coordinate decisions on initiation and termination of pilot projects, selection of trainees and other personnel, allocation of REAP resources, and/or other matters related to the achievement of REAP goals. *NOTE:* Establishment of an external advisory committee to evaluate REAP goals and progress is also strongly encouraged.
- **9.** <u>Funding.</u> REAP applicants may request recurring costs of up to \$250,000 per year for 5 years. Funds may be requested for:
  - a. Pilot Projects (see par. 5),
  - b. Associate Investigator trainees (see par. 6),
  - c. Core facility technical personnel and supplies (see par. 7),
  - d. Other miscellaneous expenses.

**10.** <u>Core Equipment and/or Facilities.</u> In addition to recurring costs, up to \$125,000 may be requested for specialized Core Equipment and/or Facilities that must be utilized by multiple REAP investigators and trainees. Requests for Core Equipment and/or Facilities needs to be well justified and include documentation of a dollar for dollar match in direct contributions and/or in-kind partnering by the VA medical center, VISN, affiliated institution, or other sources. **NOTE**: See VHA Handbook 1202.6, Shared Equipment Evaluation Program, for instructions and definitions regarding in-kind partnering and direct contributions. Specialized shared core equipment requested as part of the REAP is evaluated by the REAP review panel.

#### 11. Restrictions

- a. A VA medical center may have up to three MRS-supported REAPs and/or Centers, but may not submit more than two REAP applications at one time.
- b. REAPs must be distinct in research focus from other REAPs and/or ongoing centers at the applying VA medical center.
- c. The Director on a REAP application may not be the Director, PI, or Co-PI in any other ongoing, MRS-supported REAP and/or Center.
- d. Activities supported by the REAP are to be performed in VA facilities unless specific approval of an exception is obtained in advance of submission, in conjunction with the LOI.
- **12.** Evaluation. REAP applications are evaluated on the basis of the following major components:
  - a. Compliance with eligibility criteria;
  - b. Focus of the REAP on a medical problem of importance to the veteran population;
- c. Scientific qualifications of the Director and Qualifying Investigators, and the strength of new collaborative activities between all investigators;
- d. Plans to develop new innovative research programs via pilot projects and/or core activities and the strength of the integration of pilot projects, training program and/or core activities;
  - e. Strength of the plan for training new investigators, including a strong training history;
- f. Plans to integrate multiple basic research approaches or a combination of basic, clinical and translational approaches, where appropriate;
  - g. Strength of proposed REAP administration, including fiscal and scientific oversight;
  - h. Commitment to the REAP by the VA medical center, VISN, and affiliated institution.

- **13.** <u>Annual Performance Review.</u> Each REAP is required to submit to VA Central Office an annual research performance report. Performance measures include:
  - a. Importance of major research findings from the REAP;
- b. Productivity as indicated by the number of publications and new funding awards directly attributable to REAP Pilot projects and/or Core activities;
- c. Peer-reviewed funding of REAP Investigators in comparison to their pre-REAP funding levels;
- d. Status of the training program, including the role of trainees in REAP pilot projects and/or core activities, and trainee progress towards their next career level;
- e. Status of pilot projects including ongoing, new, concluded, and those leading to new funding awards;
- f. Evidence of local, national, and international recognition of the REAP and/or its members; and
  - g. Recommendations and/or report from External Advisory Committee.

**NOTE:** Unsatisfactory performance will result in probationary status or termination of funding.

#### 14. Competitive Renewal

- a. Previously funded REAPs are allowed to apply for competitive renewal. MRS will notify those REAPs currently eligible to apply for renewal. In addition to the evaluation criteria in Paragraph 12, renewal applications are evaluated on the following:
- (1) Enhancement of the existing program, i.e., conceptual expansion rather than simply extension of the current projects.
- (2) Success of the existing program according to measures in paragraph 13. *Note:* the success of the training program will be measured in terms of retaining VA-based investigators.
  - (3) Success of collaborative interactions within and beyond the REAP group.
  - (4) Success of core facilities and functions.
- (5) Development and refinement of new techniques or models (funding for <u>new</u> Core Equipment and/or Facilities may be requested).
  - (6) Development of inter-institutional collaborations.
  - (7) Movement towards one or more translational research modes.

- (8) Other indications of the potential for added value.
- b. REAPs that are not renewed may request phase-out funding to support completion of AI traineeships.

**NOTE**: It is expected that successful Core Facilities will have leveraged support for continuation; thus, re-funding for core functions is limited.

#### ATTACHMENT C

#### INSTRUCTIONS FOR APPLICATIONS

- 1. Submit the original application plus twelve copies of the application, duplicated on 8.5 x 11 inch white paper (see instructions for preparation of Medical Research Service Merit Review applications, on the following web site: <a href="http://www.va.gov/resdev/directive/mrs.cfm">http://www.va.gov/resdev/directive/mrs.cfm</a>). Except for the original, which needs to be duplicated face only; all forms and narrative material need to be duplicated back-to-back. Use a blank sheet of paper as a continuation sheet for the forms where necessary. MRS, Department of Veterans Affairs (VA) Central Office uses the original as the master file copy. Type material single-spaced, leaving a 1 inch margin at each edge of each sheet. Do not use small fonts, submit applications prepared from a dot matrix printer, and do not use photo reduction. Type the name of the principal investigator in the lower right portion of each numbered page.
- 2. The application needs to be complete and comprehensive as submitted. Applications are considered incomplete and returned if they are illegible, fail to follow instructions, or if the material presented is insufficient to permit an adequate review. Research Enhancement Award Program (REAP) applications must conform to a standardized format as outlined so that each application contains all of the pertinent information. This is critical to a comparative review of the applications. Limit the narrative to twenty pages (see Roman numerals I-VIII). Do not submit copies of funded or pending research applications of investigators. Each Qualifying Investigator may submit up to two reprints representing their most important work. Submit six collated sets of reprints.
- 3. The first pages of the application should be Department of Veterans Affairs (VA) Form 10-1313-1, Merit Review Application, and VA Form 10-1313-2, Summary Description of Program, followed by a Table of Contents with page numbers. Use the following designated roman numerals and headings:
  - I. Background on the Program.
  - II. Research Focus.
  - III. Personnel.
  - IV. Coordination of Activities.
  - V. Resources.
  - VI. Training.
  - VII. Advantages of a REAP Award to the VA medical center.
  - VIII. New Initiatives (Pilot Projects).
  - X. Letters of Endorsement and Support.

- XI. Budget. VA Forms 10-1313-3, Current Funds and First Year Request for Program, and VA Form 10-1313-4, Estimated Expenses of Program.
  - XI. Appendices. Under Appendices, list the following:
- A. VA Form 10-1313-5, Investigator's Biographic Sketch, and VA Form 10-1313-6, Investigator's Bibliography, limit two pages for each investigator.
- B. VA Form 10-1313-5, Investigator's Total VA and Non-VA Research Support, and VA form 10-1313-8, Summary Statement, Abstract and Budget Summary, for each funded proposal for each Qualifying Investigator.
  - C. Other relevant information.
- 4. <u>I. Background on the Program</u>. Address the history and background of your group and its interaction with your VA medical center and affiliated university in the area of the proposed REAP.
- 5. <u>II. Research Focus</u>. Describe the research focus and goals of the REAP. The central unifying theme of the REAP should be derived from the expertise and direction of the currently funded research and plans for future funded research. Describe the current status of, and future plans for, integration of basic, translational and clinical components of the REAP.
- 6. <u>III. Personnel</u>. List the name, academic title, VA title, and VA employment status (8ths) for each Qualifying Investigator. List the qualifying Merit Review or National Institute of Health (NIH) grant title, inclusive dates, and total dollars for each Qualifying Investigator. List the source, title, total amount, and inclusive dates for all other active and pending funding for each Qualifying Investigator. List other VA investigators who will participate in the REAP, and provide academic and funding information. Clearly identify the Qualifying Investigators.
- 7. IV. Coordination of Activities. Describe the composition and functions of the internal executive or steering committee. Identify the individual who is responsible for coordination of REAP activities. Describe how the activities are coordinated, including how decisions will be made to initiate or terminate pilot projects and how trainees are selected. Identify the individual responsible for administration of the funds, and describe how the funds will be administered. Describe the composition and functions of the external advisory committee.
- 8. <u>V. Resources</u>. Describe the research facilities available, both within the VA medical center and through affiliated institutions. Distinguish between those resources that are currently in place, and those resources that must be added to fulfill the REAP mission. Describe the role of the REAP in supporting the individual funded research listed in paragraph 3. If support for a core facility is requested, explain how a specialized core laboratory strengthens the research of the REAP and how the core activity supports the pilot projects. Describe the population of patients if there is a clinical component to the REAP.
- 9. **VI. Training**. List the names of current and past trainees supervised by each REAP investigator. Identify the source of funds to support each trainee, duration of training, and

current positions held by past trainees. Also list all past, current, and submitted Career Development and Merit Review Entry Program (MREP) applicants for whom the REAP investigators are mentors. Describe plans for recruitment and funding of future research trainees. Describe in detail the training program that is, or will be, in place to provide a successful training experience, including formal course work, seminars, data sessions, and plans for monitoring progress. Trainees should be supported at least in part by VA funds. Describe the potential pathway for a VA career for each proposed trainee. If funds to support trainees are not requested, explain how trainees will be encouraged to pursue a research career within the VA.

- 10. <u>VII. Advantages of a REAP Award to the VA Medical Center</u>. REAP awards are intended to provide an added dimension to a VA medical center's research activities. This includes capability and potential for a net accomplishment greater than that possible by the support of individual components alone. An explanation of how this expectation will be met is critical to the establishment of the REAP. Describe the special advantages of having this REAP at your VA medical center. Describe the anticipated impact, if any, of this REAP on the clinical care of the patients in your VA medical center.
- 11. <u>VIII. New Initiatives (Pilot Projects).</u> Describe plans to develop new and innovative projects to enhance and extend the current research activity. Collaborations among Qualifying Investigators are essential and inclusion of supporting investigators is permissible. The pilot projects should be used as a vehicle for training as well as for the exploration and development of innovative ideas. Limit the description of each project to three pages, and submit in the following format:
  - a. Names of Investigators
  - b. Title of Proposed Project
- c. **Background.** Indicate the scientific basis (rationale) for the research and its relationship to other major research findings. Describe the significance of the research, and its relevance to the mission of VA.
- d. **Research Objectives**. Outline precisely and clearly the goals of the planned project, including the hypothesis to be tested and the specific objectives of the project.
  - e. **Project Design and Methods**. Briefly define and describe the approach to the research.
  - f. References.
- 12. **IX.** Letters of Endorsement and Support. Include letters of endorsement from the medical center Director and Veterans Integrated Services Network (VISN) Director, that includes a statement agreeing to provide 25 percent protected time to the coordinator of the REAP. Include a letter of endorsement from the Research and Development Committee. Letters of support from the affiliated institution and relevant department chairperson(s) are optional, but helpful.

- 13. **X. Budget**. Use VA Form 10-1313-3 and VA Form 10-1313-4 to summarize and justify the requested budget. Include a separate VA Form 10-1313-3 and VA Form 10-1313-4 for each pilot project. Request only resources and facilities directly identified with the REAP. Allowable categories are as follows:
- a. Initial costs for technical personnel essential to maintain core or shared facilities. *NOTE:* Costs for staff supported by individual research awards are not allowed.
- b. Salary for Associate Investigator trainee(s) (M.D. or Ph.D.). *NOTE:* Medical Research Service needs to approve each AI applicant. See VHA Handbook 1201.2, Associate Investigator Program, for instructions.
- c. Specialized shared Core Equipment. If a major equipment item or specialized facility is requested, justify thoroughly and include documentation of in-kind partnering and/or direct contributions by the VA medical center, affiliated institution, or other sources. *NOTE:* See VHA Handbook 1202.6 Shared Equipment Evaluation Program, for instructions on In-kind partnering and direct contributions. A dollar-for-dollar match is required for REAP applications.
- d. Supplies and operating costs for core laboratories. *NOTE*: It is expected that Core Facilities will have leveraged support for continuation by the end of the 5-yr funding period. This should be addressed in the budget justification. Funding for competing continuation of core operating costs is limited, and requires substantial justification.
  - e. Expenses for pilot projects.
  - f. REAP infrastructure support, such as maintenance contracts on core equipment.
  - g. Travel for trainees to attend scientific meetings limited to \$3,000 per year.
  - h. Other miscellaneous expenses.

### 4. XI. Appendices

- a. **Appendix A.** Include VA Forms 10-1313-5 and VA Form 10-1313-6 for each Qualifying Investigator, followed by the same forms for other participating investigators. Limit the bibliography to two pages for each investigator.
- b. **Appendix B.** Include VA Forms 10-1313-7 and VA Form 10-1313-8 for each <u>Qualifying Investigator</u>. Include VA Form 10-1313A, Merit Review Board Summary Statement, or other funding agency front sheet, abstract and budget summary for each Federal and non-Federal funded proposal for each Qualifying Investigator.
  - c. **Appendix D.** Include other relevant information.
- 15. <u>Application Submission.</u> The application needs to be sent through the medical center Research and Development Office, the Research and Development Committee, the medical center Director, and other appropriate channels for transmittal to VHA Central Office. *NOTE*:

The notification of LOI approval will include confirmation of mailing addresses for application submission.

#### a. Submit to VHA Central Office:

- (1) The original application,
- (2) Twelve copies of the application (without Social Security Numbers), and
- (3) Six collated sets of reprints (2 reprints per investigator).

### b. Packages delivered by door-to-door couriers (e.g. Fed Ex) should be sent to:

Department of Veterans Affairs Medical Research Service (121E) 1400 Eye Street NW, Suite 400 Washington, DC 20005 Attn: REAP

c. Packages delivered by US mail should be sent to:

Department of Veterans Affairs Medical Research Service (121E) 810 Vermont Avenue NW Washington, DC 20420 Attn: REAP

# ATTACHMENT D

# CHECKLIST FOR APPLICATIONS FOR RESEARCH ENHANCEMENT AWARD PROGRAMS

1. Front sheet Department of Veterans Affairs (VA) Form 10-1313-1, Merit Review Application, signed by the Associate Chief of Staff Research and Principal Investigator (PI).
2. Abstract of the application, i.e., VA Form 10-1313-2, Summary Description of Program.
3. Table of Contents with page numbers.
4. Narrative. A maximum 20 pages containing items I-VIII.
5. Letters of Endorsement from the medical center Director and Veterans Integrated Service Network (VISN) Director.
6. Letter of Endorsement from the Research and Development (R&D) Committee.
7. Other letters of support.
8. First year budget for the program; use VA Form 10-1313-3, Current Funds and First Year Request for Program.
9. Budget summary and justification; use VA Form 10-1313-4, Estimated Expenses of Program.
10. Documentation of support from VA medical center, VISN and/or affiliated institution for shared equipment or core facilities.
11. Budget for each pilot project; use VA Forms 10-1313-3 and VA Form 10-1313-4.
12. Send a VA Form 10-1313-5, Investigator's Biographic Sketch, and a VA Form 10-1313-6, Investigator's Bibliography for each participating investigator. <i>NOTE: Limit the bibliography to two pages per investigator.</i>
13. Summary statement, abstract and budget for each federal and non-federal funded proposal for each Qualifying Investigator. Identify the investigator on each abstract.
14. Original application.
15. Twelve copies of the application (with social security numbers redacted).
16 Six collated sets of reprints (two reprints for each investigator)